AMENDMENTS TO THE CLAIMS

The following Listing of Claims replaces all prior versions, and listings, of claims in this Application.

LISTING OF CLAIMS

1. (currently amended) A needle-shaped solid pharmaceutical composition for parenteral injection~~, said composition having the shape of a needle capable of penetrating cutis or mucosa,~~ comprising a binder, ~~and~~ at least one therapeutic agent, ~~said~~ and, optionally, at least one non-crystallization ~~non-crystallisation~~ agent,

wherein the binder ~~constituting~~ constitutes at least 0.5% by weight of the composition, comprises ~~and said binder comprising~~ at least one ~~binding agent being a~~ carbohydrate binding agent, and forms an amorphous matrix,

~~and said~~ the therapeutic agent ~~comprises~~ constitutes at least ~~25%~~ 40% ~~25% by weight~~ of the composition by weight and is distributed homogeneously throughout the composition, and

the ~~said~~ composition ~~comprising optionally at least one non-crystallisation agent, whereby said binder forms an amorphous matrix, and whereby such composition~~ is injectable without dissolution or other reconstitution and ~~wherein, the therapeutic agent is distributed homogeneously throughout the composition~~ capable of penetrating cutis or mucosa.

2. (currently amended) The composition ~~according to~~ of claim 1, wherein the binder constitutes ~~from~~ 5-60% ~~by weight~~ of the composition by weight

3. (currently amended) The composition ~~according to~~ of claim 1, wherein the binder essentially remains an amorphous matrix for at least 6 months at ambient temperature.

4. (currently amended) The composition of ~~according to~~ claim 1, wherein the binder can endure a pressure force of at least 10 Newton.

5. (currently amended) The composition of ~~according to~~ claim 1, wherein the composition can endure a pressure force of at least 5 Newton.

6. (cancelled)

7. (currently amended) The composition of ~~according to~~ claim 1, wherein the composition is essentially free from entrapped air.

8. (cancelled)

9. (currently amended) The composition of ~~according to~~ claim 1, ~~having~~ wherein the composition has the shape of ~~a~~ an essentially cylindrical rod ~~essentially cylindrical and~~ comprising one pointed ~~at one~~ end.

10. (currently amended) The composition of ~~according to~~ claim 9, wherein the top angle of the rod is between 10 °C and 110 °C.

11. (currently amended) The composition according to claim ~~8 or~~ 9, wherein the maximum cross section of the composition ~~pellet~~ is less than 1 mm.

12. (currently amended) The composition of ~~according to~~ claim 9, ~~whereby~~ wherein the length of the rod is less than 10 mm.

13. (currently amended) The composition of ~~according to~~ claim 1, wherein the

volume of the composition is less than 5 µl.

14. (currently amended) The composition ~~according to~~ of claim 1, wherein the composition can penetrate the epidermis of a human being with a force less than 5 Newton.

15. (cancelled)

16. (currently amended) The composition of ~~according to~~ claim 1, wherein the binder constitutes ~~comprises~~ at most 50 % of the composition by weight ~~of the composition~~.

17. (currently amended) The composition of ~~according to~~ claim 1, wherein the at least one carbohydrate binding agent comprises from 50 % and 97 % ~~by weight~~ of the binder by weight.

18. (currently amended) The composition of ~~according to~~ claim 1, wherein the at least one non-crystallization ~~non-crystallisation~~ agent constitutes ~~comprises~~ at least 1 % ~~by weight~~ of the binder by weight.

19. (currently amended) The composition ~~according to~~ of claim 1, wherein the water content of the binder is less than 20 % by weight.

20. (currently amended) The composition of ~~according to~~ claim 1, wherein the at least one binding agent ~~being a carbohydrate~~ is a mono-, di-, or oligosaccharide or a corresponding sugar alcohol.

21. (currently amended) The composition of ~~according to~~ claim 20, wherein the at least one binding agent is ~~selected from~~ maltose, sucrose, lactose, cellobiose, trehalose,

maltulose, iso-maltulose, maltitol, sorbitol, mannitol, glucose, fructose, raffinose, melezitose, dextran, mannose, sorbose, melibiose, sophrose, turanose, lactulose, or stachyose.

22. (currently amended) The composition of ~~according to~~ claim 1, wherein the at least one ~~non-crystallisation~~ non-crystallization agent is a carbohydrate~~, said carbohydrate being~~ that is different from the binding agent.

23. (currently amended) The composition ~~according to~~ of claim 22, wherein the at least one ~~non-crystallisation~~ non-crystallization agent is a mono-, di-, or oligosaccharide, a corresponding sugar alcohol, or a derivative thereof.

24. (currently amended) The composition of ~~according to~~ claim 22, wherein the at least one ~~non-crystallisation~~ non-crystallization agent is ~~selected from~~ maltose, sucrose, lactose, cellobiose, trehalose, maltulose, iso-maltulose, maltitol, sorbitol, mannitol, glucose, fructose, raffinose, melezitose, dextran, mannose, sorbose, melibiose, sophrose, turanose, lactulose, or stachyose.

25. (currently amended) The composition ~~according to~~ of claim 1, wherein the binding agent is ~~selected from~~ maltitol, sucrose, sorbitol, ~~and~~ or mannitol and the ~~non-crystallisation~~ non-crystallization agent is ~~selected from~~ sorbitol, maltitol, ~~and~~ or mannitol.

26. (currently amended) The composition of ~~according to~~ claim 1, wherein the binding agent is maltitol and the non-crystallization ~~non-crystallisation~~ agent is sorbitol and/or sugar alcohol of maltotriose and higher oligosaccharides.

27. (currently amended) The composition of ~~according to~~ claim 1, wherein the Tg ~~(glass transition temperature)~~ of the binder is at least 30 °C.

28. (currently amended) The composition of ~~according to~~ claim 1, wherein the Tg of the binder is from 40 °C to 120 °C.

29. (currently amended) The composition of ~~according to~~ claim 1, wherein the viscosity of the composition is less than 50,000 Pa*s in a sub-range of a temperature interval between 60 °C and 140 °C.

30. (currently amended) The composition of ~~according to~~ claim 1, wherein the composition is injection moldable ~~mouldable~~ in a sub-range of the temperature interval between 60°C and 140°C.

31. (currently amended) The composition of ~~according to~~ claim 1, wherein at least 50% of the therapeutic agent is released from the composition within 60 minutes ~~min~~ after injection.

32. (currently amended) The composition according to claim 1, wherein the therapeutic agent is selected from the group consisting of analgesics, antianxiety drugs, antiarthiritic drugs, antibiotic agents, anticholinergics, antidepressants, antidiabetics, antiemetics, antihistaminics, antihypertensive agents, antiinflammatory drugs, antimigraine agents, antiparkinsonism agents, antipasmodesics, antipsychotics, antithrombotic agents, antiviral agents, appetite suppressants, blood factors, cardiovascular drugs, cerebral vasodilators, chemotherapeutic drugs, cholinergic agonists, contraceptives, coronary agents, diuretics, hormonal agents, immunosuppressive agents, growth factors, narcotic antagonists, opiods, peripheral asodilators, tranquilizers, vaccines, immunogenic agents, and ~~immunising~~ immunization agents.

33. (currently amended) The composition of ~~according to~~ claim 1, wherein the therapeutic agent is selected from the group consisting of hormones, lipids, nucleic acids, nucleotides, oligonucleotides, oligosaccharides, organics, peptide mimetics, antibodies, peptides, polysaccharides, and proteins.

34. (currently amended) The composition of ~~according to~~ claim 1, wherein the therapeutic agent is selected from the group consisting of proteins, peptides, and polypeptides, ~~said~~ wherein the protein, peptide, or polypeptide ~~being~~ is amorphous or crystalline.

35. (currently amended) The composition of ~~according to~~ claim 1, wherein the therapeutic agent is selected from the group consisting of hormones, antidiabetic drugs, growth factors, and blood factors.

36-38 (cancelled)

39. (currently amended) The composition of ~~according to~~ claim 1, wherein the composition is provided with a coating.

40. (currently amended) A method for preparing a solid pharmaceutical composition for parenteral injection comprising[,] mixing at least one therapeutic agent that constitutes at least 40% of the composition by weight homogeneously with a binder~~, obtaining an amorphous melt matrix, wherein the binder~~ that comprises at least one carbohydrate binding agent ~~being a carbohydrate~~ and constitutes 0.5-60% of the composition by weight, and, optionally, at least one non-crystallization ~~non-crystallisation~~ agent, so as to obtain an amorphous melt matrix ~~said binder constituting at least 0.5% by weight of the composition and at most 75% by weight of the composition, and said therapeutic agent comprising at least 25% by weight of the composition~~, shaping the melt matrix to a predetermined geometry, cooling to below the Tg ~~(glass transition~~

~~temperature)~~ of the binder ~~obtaining the composition~~, and removing the composition from the ~~mould~~ mold cavity.

41. (currently amended) The method ~~according to~~ of claim 40, wherein the melt is injected into a ~~mould~~ mold cavity having a predetermined geometry.

42. (currently amended) The method ~~according to~~ of claim 40, wherein the method ~~further comprising a heating step~~ comprises applying heat to obtain ~~the~~ an amorphous matrix prior to mixing the therapeutic agent and binder ~~composition~~.

43. (currently amended) The method of ~~according to~~ claim 40, wherein, prior to melting, the binder is dissolved in a solvent~~, dried,~~ and dried to ~~obtaining~~ a solid amorphous matrix, and, optionally, disintegrated ~~disintegrating the binder~~ into a powder.

44. (currently amended) The method of ~~according to~~ claim 40, wherein the binder and the at least one therapeutic agent are mixed homogeneously as powders and the mixture is melted to form the melt ~~afterwards~~.

45. (currently amended) The method ~~according to~~ of claim 43, wherein the solvent is water.

46. (currently amended) The method of ~~according to~~ claim 40, wherein the water content of the composition is less than 20 % by weight.

47. (currently amended) The method of ~~according to~~ claim 40, wherein the Tg of the binder is at least 30°C.

48. (currently amended) The method of ~~according to~~ claim 40, wherein the viscosity of the composition is less than 50,000 Pa*s in a sub-range of the temperature interval between 60°C and 140°C.

49. (currently amended) The method of ~~according to~~ claim 40, wherein the ~~steps of the~~ method ~~are carried out~~ is performed under essentially aseptic conditions ~~aseptically~~.

50. (currently amended) The method of ~~according to~~ claim 40, wherein the composition is molded as the second part in a two component molding machine.

51. (currently amended) The method of ~~according to~~ claim 50, wherein a cartridge constituting the mold cavity is molded as the first part in a two component molding machine.

52. (currently amended) A ~~The~~ method of injecting a solid pharmaceutical composition ~~as defined by claim 1~~ through epidermis or mucosa comprising positioning ~~arranging~~ a device comprising the solid composition of claim 1 adjacent to the epidermis or mucosa and ejecting the solid composition so as to inject the composition through the epidermis or mucosa.

53. (currently amended) The method of ~~according to~~ claim 52, wherein the animal is selected from the group consisting of fish, birds, ~~molluses~~ mollusks, reptiles, ~~or~~ and mammals.

54. (currently amended) The method of ~~according to~~ claim 52, wherein the composition is injected at least once a day.

55. (currently amended) A method of immunizing a mammal against a disease comprising performing the method of claim 52 using a composition wherein the therapeutic

agent promotes an immunity-conferring response in the mammal ~~The method according to claim 52 for immunisation~~.

56-58. (cancelled)

59. (currently amended) The method ~~according to~~ of claim 52, wherein the animal is ~~man~~ a human.

60. (new) The composition of claim 1, wherein the composition comprises a pellet-shaped section having a substantially cylindrical, triangular, square, or polygonal cross section.

61. (new) The composition of claim 1, wherein the binder does not reduce the stability of the therapeutic agent.

62. (new) The composition of claim 1, wherein both the at least one binding agent and the at least one non-crystallization agent are non-reducing sugars.

63. (new) The composition of claim 1, wherein the composition comprises an additive selected from the group consisting of preservatives, adjuvants, stabilizers, lubricants, and disintegraters.

64. (new) A solid needle-shaped pharmaceutical composition comprising a binder that forms an amorphous matrix, at least one therapeutic agent, and, optionally, at least one non-crystallization agent, wherein the binder consists essentially of maltitol and the composition is capable of penetrating cutis or mucosa by injection without dissolution or other reconstitution.

65. (new) The composition of claim 64, wherein the composition comprises one or

more non-crystallization agents selected from the group consisting of sorbitol, hydrogenated oligosaccharides, and combinations thereof.

66. (new) A solid needle-shaped pharmaceutical composition comprising a binder that forms an amorphous matrix and at least one therapeutic agent, and, optionally, at least one non-crystallization agent, wherein the composition is primarily composed of maltitol and the composition is capable of penetrating cutis or mucosa by injection without dissolution or other reconstitution.

67. (new) The composition of claim 66, wherein the composition comprises one or more non-crystallization agents selected from the group consisting of sorbitol, hydrogenated oligosaccharides, and combinations thereof.

68. (new) The composition of claim 1, wherein the therapeutic agent is a protein, peptide, or polypeptide.